IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

SANTARUS, INC., a Delaware corporation, and THE CURATORS OF THE UNIVERSITY OF MISSOURI, a public corporation and body politic of the State of Missouri,	)	
Plaintiffs,	)	C.A. No. 07-827-GMS
v.	)	
PAR PHARMACEUTICAL, INC., a Delaware corporation,	)	
Defendants	)	

ANSWER

Defendant, Par Pharmaceutical, Inc. ("Par"), by their attorneys, respond to the averments made in the numbered paragraphs of the complaint for patent infringement ("complaint") filed by Plaintiffs, Santarus, Inc. and The Curators of the University of Missouri (collectively "Plaintiffs"), as follows:

ANSWER

Complaint Paragraph 1: Santarus is a corporation organized and existing under the laws of Delaware, having a principal place of business at 10590 West Ocean Air Drive, Suite 200, San Diego, California 92130. Santarus is a specialty pharmaceutical company focused on acquiring, developing and commercializing products for the prevention and treatment of gastrointestinal diseases and disorders.

Answer: On information and belief, Par admits that Santarus is a corporation organized and existing under the laws of Delaware, having a principal place of business at 10590 West Ocean Air Drive, Suite 200, San Diego, California 92130. Par is without sufficient information to admit or deny the remaining allegations of paragraph 1 and, therefore, denies the same.

Complaint Paragraph 2: The University is a public corporation and body politic, an arm or instrumentality of state government in the state of Missouri, having a place of business at 321 University Hall, Columbia, Missouri 65211.

Answer: On information and belief, Par admits that The University of Missouri has a place of business at 321 University Hall, Columbia, Missouri 65211. Par is without sufficient information to admit or deny the remaining allegations of paragraph 2 and, therefore, denies the same.

Complaint Paragraph 3: Plaintiffs are informed and believe, and thereon allege, that Defendant is a corporation organized and existing under the laws of Delaware with a principal place of business at 300 Tice Boulevard, Woodcliff Lake, New Jersey 07677. Defendant is one of the largest manufacturers and distributors of generic pharmaceutical products. Defendant conducts business throughout the United States, including in this District.

Answer: Par admits the allegations in the first and third sentences of paragraph 3. Par admits that it manufactures and distributes, *inter alia*, generic pharmaceutical products in the United States, and states that its size is a matter of public record. Par denies any remaining allegations of Paragraph 3.

Complaint Paragraph 4: This is an action for patent infringement arising under the patent laws of the United States of America, 35 U.S.C. § 1, et seq., including § 271. This Court has subject matter jurisdiction over the matters asserted herein under 28 U.S.C. §§ 1331 and 1338(a).

Answer: In response to the allegations of paragraph 4, Par admits that Plaintiffs purport to bring this action under Title 35, United States Code. Par states that it does not contest subject-matter jurisdiction. Par denies the remaining allegations in paragraph 4, and expressly denies any allegation of patent infringement and denies that Plaintiffs are entitled to any relief.

Complaint Paragraph 5: Defendant is subject to personal jurisdiction in this District because it is incorporated in Delaware, conducts business in this District, purposefully avails itself of the rights and benefits of Delaware law, and has substantial and continuing contacts with Delaware.

Answer: In response to the allegations in paragraph 5, Par states that it does not contest personal jurisdiction in Delaware for the purposes of this action.

Complaint Paragraph 6: Venue is proper in this judicial district pursuant to 28 U.S.C. §§ 1391(b)-(d) and 1400(b).

Answer: In response to the allegations of paragraph 6, Par states that it does not contest venue in this judicial district for the purposes of this action.

Complaint Paragraph 7: On March 2, 2004, the United States Patent and Trademark Office (the "PTO") issued U.S. Patent No. 6,699,885, entitled "Substituted Benzimidazole Dosage Forms and Methods of Using Same" to the University, the assignee of the named inventor Jeffrey O. Phillips.

Answer: In response to paragraph 7 of the complaint, Par states that the face of the '885 patent speaks for itself with respect to the date of issue, the title, and the named inventor. Par is without sufficient information to admit or deny the remaining allegations in paragraph 7, and therefore denies the same.

Complaint Paragraph 8: On or about August 22, 2005, reexamination of U.S. Patent No. 6,699,885 by the PTO was requested by a third party, which was granted by the PTO. On or about March 13, 2007, the reexamination proceedings concluded with the PTO issuing a Notice of Intent to Issue a Reexamination Certificate confirming that all claims of the patent "are determined to be patentable as amended." On September 18, 2007, the PTO issued a

Reexamination Certificate confirming that all claims as amended are "determined to be patentable." In the Reexamination Certificate, claims 1 and 26 were amended, and claims 52 and 53 were added. A copy of U.S. Patent No. 6,669,885 and its Ex Parte Reexamination Certificate (5894th) are attached hereto as Exhibits A and B, respectively, and shall be hereafter referred to collectively as the "'885 Patent."

Answer: In response to paragraph 8 of the complaint, Par admits only (1) that PTO records state that on or about August 22, 2005, a request for reexamination of the '885 Patent was filed with the PTO and was subsequently granted by the PTO, (2) on or about March 13, 2007, the PTO records indicate that the PTO issued a Notice of Intent to Issue a Reexamination Certificate, (3) PTO records indicate that on September 18, 2007, the PTO issued a Reexamination Certificate, (4) PTO records indicate that during the Reexamination proceedings, claims 1 and 26 were amended, and claims 52 and 53 were added. Par also admits that what appears to be a copy of the '885 patent is attached as Exhibit A to the complaint and what appears to be a copy of Ex Parte Reexamination Certificate (5894th) is attached to the complaint as Exhibit B. Par is denies the remaining allegations of paragraph 8.

Complaint Paragraph 9: On December 3, 2002, the PTO issued U.S. Patent No. 6,489,346 (the "'346 Patent"), entitled "Substituted Benzimidazole Dosage Forms and Method of Using Same" to the University, the assignee of the named inventor Jeffrey O. Phillips. A copy of the '346 Patent is attached hereto as Exhibit C.

Answer: In response to paragraph 9 of the complaint, Par admits only that what appears to be a copy of the '346 patent is attached as Exhibit C to the complaint and states that the face of the '346 patent speaks for itself with respect to the issue date, the title and the named inventor. Par denies any remaining allegations in paragraph 9.

Complaint Paragraph 10: On November 11, 2003, the PTO issued U.S. Patent No. 6,645,988 (the "'988 Patent"), entitled "Substituted Benzimidazole Dosage Forms and Method of Using Same" to the University, the assignee of the named inventor Jeffrey O. Phillips. A copy of the '988 Patent is attached hereto as Exhibit D.

Answer: In response to paragraph 10 of the complaint, Par admits only that what appears to be a copy of the '988 patent is attached as Exhibit D to the complaint and states that the face of the '988 patent speaks for itself with respect to the issue date, the title, and the named inventor. Par denies any remaining allegations in paragraph 10.

Complaint Paragraph 11: On August 24, 2004, the PTO issued U.S. Patent No. 6,780,882 (the "'882 Patent"), entitled "Substituted Benzimidazole Dosage Forms and Method of Using Same" to the University, the assignee of the named inventor Jeffrey O. Phillips. A copy of the '882 Patent is attached hereto as Exhibit E.

Answer: In response to paragraph 11 of the complaint, Par admits only that what appears to be a copy of the '882 patent is attached as Exhibit E to the complaint and states that the face of the '882 patent speaks for itself with respect to the issue date, the title, and the named inventor. Par denies any remaining allegations in paragraph 11.

Complaint Paragraph 12: The University is the record owner of the '885, '346, '988, and '882 patents (collectively the "Patents-in-Suit"), and Santarus is the exclusive licensee. Plaintiffs have the right to sue to enforce the Patents-in-Suit.

Answer: Par is without information sufficient to admit or deny the allegations of paragraph 12 and, therefore, denies the same.

Complaint Paragraph 13: The Patents-in-Suit are listed in the United States Food and Drug Administration's (the "FDA") *Approved Drug Products with Therapeutic Equivalence*

Evaluations, commonly known as the Orange Book, in support of Santarus' Zegerid® (omeprazole/sodium bicarbonate) Powder for Oral Suspension 20 mg and 40 mg ("Zegerid®") products. Zegerid® is indicated for the treatment of heartburn and other symptoms of gastroesophageal reflux disease, the treatment and maintenance of healing of erosive esophagitis, and the short-term treatment of active duodenal ulcers and active benign gastric ulcers. Zegerid® is the first and only immediate-release oral proton pump inhibitor approved by the FDA. Zegerid® is marketed by Santarus.

Answer: With respect to paragraph 13 of the complaint, Par admits only that it appears that Santarus caused the Patents-in-Suit to be listed in the FDA Orange Book with respect to Santarus's Zegerid® (omeprazole/sodium bicarbonate) Powder for Oral Suspension 20 mg and 40 mg ("Zegerid®") products and that the labeling for NDA No. 21-636 approved on June 15, 2004 states that Zegerid® is indicated for the treatment of heartburn and other symptoms associated with gastroesophageal reflux disease, the short-term treatment (4-8 weeks) of erosive esophagitis which has been diagnosed by endoscopy, to maintain healing of erosive esophagitis, and the short-term treatment of active duodenal ulcer. Par is without sufficient information to admit or deny the remaining allegations of paragraph 13 and, therefore, denies the same.

Complaint Paragraph 14: On information and belief, Defendant has submitted Abbreviated New Drug Application No. 79-182 (the "ANDA") to the FDA under § 505(j) of the Federal Food, Drug and Cosmetic Act (21 U.S.C. § 355(j)). The ANDA seeks approval to market omeprazole and sodium bicarbonate powder for oral suspension, 20 mg/1680 mg (the "Proposed 20 mg Powder") and 40 mg/1680 mg (the "Proposed 40 mg Powder"), generic versions of Zegerid®, prior to the expiration of the Patents-in-Suit.

Answer: Par admits the allegations of the first sentence of paragraph 14. Par admits that it has requested FDA to approve the ANDA before the July 16, 2016 expiration of the patents-in-suit, and that the ANDA product is omeprazole and sodium bicarbonate powder for oral suspension, 20mg/1680mg, and 40 mg/1680mg. Par denies the remaining allegations of paragraph 14.

Complaint Paragraph 15: Plaintiffs received a letter dated November 13, 2007, from Defendant notifying them that the ANDA includes a certification under 21 U.S.C. § 355(j)(2)(A)(vii)(IV) (the "First Paragraph IV Certification") that, in Defendant's opinion, the Patents-in-Suit are invalid, unenforceable or will not be infringed by the commercial manufacture, use or sale of the Proposed 20 mg Powder.

Answer: On information and belief, Par admits the allegations of paragraph 15.

Complaint Paragraph 16: Plaintiffs received a letter dated December 6, 2007, from Defendant notifying them that the ANDA includes a certification under 21 U.S.C. § 355(j)(2)(A)(vii)(IV) (the "Second Paragraph IV Certification") that, in Defendant's opinion, the Patents-in-Suit are invalid, unenforceable or will not be infringed by the commercial manufacture, use or sale of the Proposed 20 mg and 40 mg Powder.

Answer: On information and belief, Par admits the allegations of paragraph 16.

Complaint Paragraph 17: Plaintiffs commenced this action within 45 days of receiving the First and Second Paragraph IV Certifications.

Answer: Par is without sufficient information to admit or deny the allegations of paragraph 17 and, therefore, denies the same.

Complaint Paragraph 18: Plaintiffs incorporate by reference paragraphs 1 through 17.

Answer: Par's responses to the allegations of paragraphs 1 through 17 are incorporated by reference as if fully set forth herein.

Complaint Paragraph 19: The submission of the ANDA to the FDA, including the First and Second Paragraph IV Certifications, constitutes infringement of the '885 Patent under 35 U.S.C. § 271(e)(2). Moreover, any commercial manufacture, use, offer to sell, sale or import of the Proposed 20 mg and 40 mg Powder would infringe the '885 Patent under 35 U.S.C. § 271(a)-(c).

Answer: Par denies the allegations of paragraph 19.

Complaint Paragraph 20: Defendant has been aware of the existence of the '885 Patent prior to filing the ANDA, and has no reasonable basis for believing that the Proposed 20 mg and 40 mg Powder will not infringe the '885 Patent. This case is, therefore, "exceptional" within the meaning of 35 U.S.C. § 285.

Answer: Par admits that it was aware of the existence of the '885 Patent prior to filing the ANDA. Par denies the remaining allegations of paragraph 20.

Complaint Paragraph 21: Defendant's infringing activities will irreparably harm Plaintiffs unless enjoined by this Court. Plaintiffs do not have an adequate remedy at law.

Answer: Par denies the allegations of paragraph 21.

Complaint Paragraph 22: Plaintiffs incorporate by reference paragraphs 1 through 17.

Answer: Par's responses to the allegations of paragraphs 1 through 17 are incorporated by reference as if fully set forth herein.

Complaint Paragraph 23: The submission of the ANDA to the FDA, including the First and Second Paragraph IV Certifications, constitutes infringement of the '346 Patent under 35 U.S.C. § 271(e)(2). Moreover, any commercial manufacture, use, offer to sell, sale or import of

the Proposed 20 mg or 40 mg Powder would infringe the '346 Patent under 35 U.S.C. § 271(a)-(c).

Answer: Par denies the allegations of paragraph 23.

Complaint Paragraph 24: Defendant has been aware of the existence of the '346 Patent prior to filing the ANDA, and has no reasonable basis for believing that the Proposed 20 mg and 40 mg Powder will not infringe the '346 Patent. This case is, therefore, "exceptional" within the meaning of 35 U.S.C. § 285.

Answer: Par admits that it was aware of the existence of the '346 Patent prior to filing the ANDA. Par denies the remaining allegations of paragraph 24.

Complaint Paragraph 25: Defendant's infringing activities will irreparably harm Plaintiffs unless enjoined by this Court. Plaintiffs do not have an adequate remedy at law.

Answer: Par denies the allegations of paragraph 25.

Complaint Paragraph 26: Plaintiffs incorporate by reference paragraphs 1 through 17.

Answer: Par's responses to the allegations of paragraphs 1 through 17 are incorporated by reference as if fully set forth herein.

Complaint Paragraph 27: The submission of the ANDA to the FDA, including the First and Second Paragraph IV Certifications, constitutes infringement of the '988 Patent under 35 U.S.C. § 271(e)(2). Moreover, any commercial manufacture, use, offer to sell, sale or import of the Proposed 20 mg or 40 mg Powder would infringe the '988 Patent under 35 U.S.C. § 271(a)-(c).

Answer: Par denies the allegations of paragraph 27.

Complaint Paragraph 28: Defendant has been aware of the existence of the '988 Patent prior to filing the ANDA, and has no reasonable basis for believing that the Proposed 20 mg or

40 mg Powder will not infringe the '988 Patent. This case is, therefore, "exceptional" within the meaning of 35 U.S.C. § 285.

Answer: Par admits only that it was aware of the existence of the '988 Patent prior to filing the ANDA. Par denies the remaining allegations of paragraph 28.

Complaint Paragraph 29: Defendant's infringing activities will irreparably harm Plaintiffs unless enjoined by this Court. Plaintiffs do not have an adequate remedy at law.

Answer: Par denies the allegations of paragraph 29.

Complaint Paragraph 30: Plaintiffs incorporate by reference paragraphs 1 through 17.

Answer: Par's responses to the allegations of paragraphs 1 through 17 are incorporated by reference as if fully set forth herein.

Complaint Paragraph 31: The submission of the ANDA to the FDA, including the First and Second Paragraph IV Certifications, constitutes infringement of the '882 Patent under 35 U.S.C. § 271(e)(2). Moreover, any commercial manufacture, use, offer to sell, sale or import of the Proposed 20 mg or 40 mg Powder would infringe the '882 Patent under 35 U.S.C. § 271 (a)-(c).

Answer: Par denies the allegations of paragraph 31.

Complaint Paragraph 32: Defendant has been aware of the existence of the '882 Patent prior to filing the ANDA, and has no reasonable basis for believing that the Proposed 20 mg and 40 mg Powder will not infringe the '882 Patent. This case is, therefore, "exceptional" within the meaning of 35 U.S.C. § 285.

Answer: Par admits that it was aware of the existence of the '882 Patent prior to filing the ANDA. Par denies the remaining allegations of paragraph 32.

Complaint Paragraph 33: Defendant's infringing activities will irreparably harm Plaintiffs unless enjoined by this Court. Plaintiffs do not have an adequate remedy at law.

Answer: Par denies the allegations of paragraph 33.

RESPONSE TO PRAYER FOR RELIEF

Par denies that Plaintiffs are entitled to any of the relief that they seek in their prayer for relief or otherwise.

DEFENSES

Without any admission as to the burden of proof or as to any of the allegations in the Complaint, Par states the following defenses.

First Defense

1. Each purported claim for relief in the Complaint is barred for failure to state a claim upon which relief can be granted.

Second Defense

2. Par's omeprazole and sodium bicarbonate capsules that are the subject of ANDA No. 79-182 (the "Proposed Products") do not infringe, and would not infringe, (directly, indirectly, contributorily or by inducement) any valid or enforceable claim of the Patents-in-Suit.

Third Defense

3. By reason of the prior art and/or statements and representations made to the United States Patent and Trademark Office during the prosecution of the application that led to the issuance of the Patents-in-Suit, the Patents-in-Suit are so limited that no claim can be construed as covering any Par activity.

Fourth Defense

4. Each and every asserted claim of the Patents-in-Suit is invalid for failure to meet one or more of the requirements of Title 35, United States Code, including Sections 101, 102, 103, and 112 and for improper double patenting.

Fifth Defense

5. Par's actions in defending this case do not give rise to an exceptional case under 35 U.S.C. § 285.

Sixth Defense

6. Par has not willfully infringed any claim of the Patents-in-Suit.

Seventh Defense

7. Plaintiff's claims and requested relief are barred by the doctrine of estoppel.

Eighth Defense

8. Plaintiff's claims and requested relief are barred by the doctrine of waiver.

Ninth Defense

9. Plaintiff's claims and requested relief are barred by the doctrine of laches.

WHEREFORE, Par demands judgment in its favor and against Santarus, Inc. and The Curators of the University of Missouri as follows:

(a) Dismissing the complaint with prejudice and denying each request for relief made by Santarus, Inc. and/or The Curators of the University of Missouri;

(b) Holding the '988 patent not infringed by the making, use, sale, offer for sale, marketing, or importation of Par's Proposed Products and not infringed by any process used to make Par's Proposed Products;

(c) Holding the '346 patent not infringed by the making, use, sale, offer for sale, marketing, or importation of Par's Proposed Products and not infringed by any process used to make Par's Proposed Products;

(d) Holding the '885 patent not infringed by the making, use, sale, offer for sale, marketing, or importation of Par's Proposed Products and not infringed by any process used to make Par's Proposed Products;

(e) Holding the '882 patent not infringed by the making, use, sale, offer for sale, marketing, or importation of Par's Proposed Products and not infringed by any process used to make Par's Proposed Products;

(f) Holding the '988 patent and all its claims invalid;

(g) Holding the '346 patent and all its claims invalid;

(h) Holding the '885 patent and all its claims invalid;

(i) Holding the '882 patent and all its claims invalid;

(j) Adjudging this to be an exceptional case under 35 U.S.C. § 285;

(k) Awarding Par its attorney's fees;

(l) Awarding Par its costs and expenses; and

(m) Awarding Par such other and further relief as the Court deems just and proper.

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Dated: January 10, 2008

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IN THE UNITED STATES DISTRICT COURT
DISTRICT OF DELAWARE

CERTIFICATE OF SERVICE

I hereby certify that on January 10, 2008, I electronically filed the foregoing document with the Clerk of Court using CM/ECF which will send notification of such filing(s) and Hand Delivered to the following:

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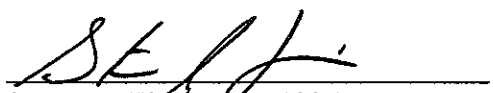

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